

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OPPTS 870.1300)
LIMIT TEST

Product Manager: 31
MRID No.: 465039-07

Reviewer: DynCorp/CSC and Ian Blackwell
Study Completion Date: April 28, 2004
Report No.: 04-048-5

Testing Laboratory: Tox Monitor Laboratories, Inc.
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Quality Assurance (40 CFR §160.12): A Quality Assurance Statement was provided. A statement of Good Laboratory Practice (GLP) compliance also was included stating that the study meets the requirements of 40 CFR Part 160.

Test Material: BTC 2125M-RTU 200 Sanitizer / Ref. # 2761-85 / clear liquid

Species: 10 Sprague-Dawley derived, albino rats
Sex: 5 Males and 5 Females; females were nulliparous and non-pregnant
Age: Young adult; 6 - 10 weeks
Weight: 201 - 236 grams
Source: Harlan Sprague Dawley, Indianapolis, Indiana
Housing: Temperature Range: Information not provided
Relative Humidity: Information not provided
Photoperiod: Information not provided
Acclimation: At least 5 days

Concentration:

Group	Gravimetric Exposure Concentration (mg/L)	Nominal Concentration (mg/L)
I	2.64	79

Summary:

1. **LC₅₀ (mg/L) 4-hr exposure:** Males > 2.64 mg/L
Females > 2.64 mg/L
Combined > 2.64 mg/L
2. **The estimated 4-hr exposure LC₅₀ is > 2.64 mg/L.**
3. **MMAD:** 5.07 µm (Sample 1 - 100 minutes)
4.55 µm (Sample 2 - 200 minutes)
4. **Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviation From 870.1300):

- No deviations were reported by the laboratory.
- The lower age limit of the rats was below that specified by the guidelines.
- The temperature range, relative humidity and photoperiod of animal housing was not specified.
- The MMAD particle size in both samples was greater than the 1 - 4 µm range specified by the guidelines.
- The lower temperature value of the chamber was below that suggested by the guidelines.
- Relative humidity of the chamber was above 95 % for most of the exposure period. The guidelines recommend maintaining relative humidity between 30 - 70 %.

- Changes in body weights were recorded but not calculated.
- The method of randomization in assigning animals to test groups was not provided.

Results:

Reported Mortality

Exposure Concentration (mg/L)	Number of deaths / number tested		
	Males	Females	Combined
2.64	0 / 5	0 / 5	0 / 5

Chamber Atmosphere

Exposure conc. (mg/L)	Sample	MMA D (µm)	GSD (µm)	% Particles at Effective Cutoff Diameter (Cumulative)							
				<0.4 µm	<0.7 µm	<1.1 µm	<2.1 µm	<3.3 µm	<4.7 µm	<5.8 µm	< 9 µm
2.64	1	5.07	3.91	0.0	6.1	15.4	26.4	37.6	48.2	55.5	63.5
	2	4.55	3.75	0.0	6.7	16.6	29.0	40.2	49.0	57.9	67.6

Chamber Environment During Exposure

Exposure Level (mg/L)	2.64
Chamber Volume (L)	400
Airflow (Lpm)	83
Temperature (°C)	18.9 - 20.0
Relative Humidity (%)	46 - 95+

Clinical Observations: No mortality was observed in any of the ten test animals. All animals appeared inactive, but otherwise normal, after 30 minutes of exposure through the end of the exposure period. Upon removal from the chamber, all animals were inactive, but otherwise normal and exhibited slightly wet fur from the test spray. All animals appeared normal following the exposure and through the end of the 14-day observation period. Body weight gain was noted for all ten test animals over the duration of the study.

Gross Necropsy Findings: No gross abnormalities were noted for any of the test animals when necropsied at the conclusion of the 14-day observation period.